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10/574,476	10/05/2006	Masao Sudoh	Q94153	2354
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SUGHRUE-265550			EXAMINER	
2100 PENNSYLVANIA AVE. NW			SZNAIDMAN, MARCOS L	
WASHINGTON, DC 20037-3213				
ART UNIT		PAPER NUMBER		
1612				
NOTIFICATION DATE		DELIVERY MODE		
03/29/2010		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/574,476

Applicant(s)

SUDOH ET AL.

Examiner

MARCOS SZNAIDMAN

Art Unit

1612

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 January 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3, 5-12, 14 and 15 is/are pending in the application.
- 4a) Of the above claim(s) 14 and 15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3 and 5-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB06)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

This office action is in response to applicant's reply filed on January 26, 2010.

Receipt of Declarations under 37 CFR 1.132 is acknowledged.

Status of Claims

Amendment of claim 3 is acknowledged

Claims 1, 3, 5-12 and 14-15 are currently pending and are the subject of this office action.

Claims 14-15 were withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on December 18, 2007.

Claims 1, 3, and 5-12 are presently under examination.

Priority

The present application is a 371 of PCT/JP04/14896 filed on 10/01/2004, and claims priority to foreign application: JAPAN 2003-345125 filed on 10/03/2003.

Rejections and/or Objections and Response to Arguments

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated (Maintained Rejections and/or Objections) or newly applied (New Rejections and/or Objections,

Necessitated by Amendment or New Rejections and/or Objections not Necessitated by Amendment). They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 103 (Maintained Rejection)

Claims 1, 3, and 5-12 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Toda et. al. (US 6,608,221) in view of Black (US 6,043,223, cited in prior office action) or Sakanaka (US 2003/0104079, cited in prior office action).

The reasons for this rejection have been provided in the previous office action dated August 26, 2009, the text of which is incorporated by reference herein.

Applicant's arguments have been fully considered but are not persuasive.

Applicant argues that:

Regarding evidence of non-obviousness, Applicants submit herewith a Declaration Under 37 C.F.R. § 1.132 executed by Mr. Seichi Tanikawa, a co-inventor of the presently claimed invention. As indicated in the § 132 Declaration enclosed herewith, the infusion preparation of the present invention makes a water-insoluble (2R)-2-propyloctanoic acid soluble in water and does not require the operation such as dissolution or dilution at the time of use.

Although the cited publications disclose that bradykinin and ginsenoside can be used as an infusion preparation, the remarkable unexpectedly superior effects of the present invention cannot be expected from the cited publications, and therefore the prior art publications do not render the presently claimed invention obvious. Namely, the results show that even if the pH changes as a result of mixing with other pharmaceutical agent, neither clouding nor precipitation occurs.

Further, the stability is excellent. As shown in the data, in the infusion preparation of the present invention, (2R)-2-propyloctanoic is stable. As set forth in the Results section of the § 132 Declaration, the residual ratio of (2R)-2-propyloctanoic is 95% or more after preservation of 48 hours in the infusion preparation of the present invention. Normally, fatty acids such as (2R)- 2-propyloctanoic acid, wherein a carbon atom in a-position has a hydrogen atom, tend to show isomerization/racemization by alkalinizing liquid. However, in the infusion preparation of the present invention, it is unexpectedly stable. Accordingly, in view of the unexpectedly superior and remarkable effects of the present claimed invention, Toda in view of Black or Sakanaka do not render the present claimed invention obvious.

Examiner's response:

MPEP 716.02 states: "Whether the unexpected results are the result of unexpectedly improved results or a property not taught by the prior art, the "objective evidence of nonobviousness must be commensurate in scope with the claims which the

evidence is offered to support.” In other words, the showing of unexpected results must be reviewed to see if the results occur over the entire claimed range. *In re Clemens*, 622 F.2d 1029, 1036, 206 USPQ 289, 296 (CCPA 1980) (Claims were directed to a process for removing corrosion at “elevated temperatures” using a certain ion exchange resin (with the exception of claim 8 which recited a temperature in excess of 100C). Appellant demonstrated unexpected results via comparative tests with the prior art ion exchange resin at 110C and 130C. The court affirmed the rejection of claims 1-7 and 9-10 because the term “elevated temperatures” encompassed temperatures as low as 60C where the prior art ion exchange resin was known to perform well. The rejection of claim 8, directed to a temperature in excess of 100C, was reversed.). See also *In re Peterson*, 315 F.3d 1325, 1329-31, 65 USPQ2d 1379, 1382-85 (Fed. Cir. 2003) (data showing improved alloy strength with the addition of 2% rhenium did not evidence unexpected results for the entire claimed range of about 1-3% rhenium); *In re Grasselli*, 713 F.2d 731, 741, 218 USPQ 769, 777 (Fed. Cir. 1983) (Claims were directed to certain catalysts containing an alkali metal. Evidence presented to rebut an obviousness rejection compared catalysts containing sodium with the prior art. The court held this evidence insufficient to rebut the prima facie case because experiments limited to sodium were not commensurate in scope with the claims.).”

Although Applicant was able to demonstrate unexpected results (i.e. soluble and stable solutions) for the infusion preparation comprising (2R)-2-propyloctanoic acid for a narrow set of conditions, the data provided by Applicant in the specification and in the 1.132 declaration is not commensurate in scope with the claims.

The data provided by Applicant (see specification, Examples 1-1 through 4-2 on pages 31-37) shows infusion preparations comprising (2R)-2-propyloctanoic acid in concentrations from 2 mg/mL to 4 mg/mL, instead of the much broader range of 0.01 mg/mL to 20 mg/mL claimed. The only basic metal ion salts utilized in the examples are: trisodium phosphate-dodecahydrate and disodium hydrogen phosphate-dodecahydrate in a 1.6:1 to 1.8:1 weight ratio with (2R)-2-propyloctanoic acid, instead of the vast array of salts listed in claims 1 and 5 in a 1:1 to 1:5 ratio. All the examples contain sodium chloride in a specific amount (900 mg in 100 mL of water) and some contain glucose in a specific amount (5 mg in 100 mL of water) instead of electrolytes, saccharides, vitamins and protein amino acids as claimed in claim 3.

According to Applicant (2R)-2-propyloctanoic acid is very insoluble in water. The solubility of a compound in a specific solvent depends on many factors, among those: concentration of the compound, presence or absence of other electrolytes, and formation of salts. Since (2R)-2-propyloctanoic is so insoluble in water, it is expected that only a narrow set of conditions, like the ones disclosed above by Applicant, will solubilize it in water: i.e. a specific electrolyte like sodium chloride, a specific basic metal ion salt like trisodium phosphate-dodecahydrate and disodium hydrogen phosphate-dodecahydrate in very specific ratio, etc. As such, the unexpected results claimed by Applicant for the narrow set of conditions presented in the above examples can not be extrapolated to the much broader set of conditions claimed.

Withdrawn Rejections and/or Objections

Claims rejected under 35 USC 112, second paragraph.

Due to applicant's amendment of claim 3, the 35 USC 112, second paragraph rejection is now moot.

Rejection under 35 USC 112, second paragraph is withdrawn.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARCOS SZNAIDMAN whose telephone number is (571)270-3498. The examiner can normally be reached on Monday through Thursday 8 AM to 6 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MARCOS SZNAIDMAN/
Examiner, Art Unit 1612
March 23, 2010.

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612

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